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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,688	05/14/2001	David N. Cooper	WCM78	6577

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EXAMINER	
MYERS, CARLA J	

ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

1. The amendment filed on September 8, 2003 canceling all claims drawn to the elected invention and presenting only new claims not drawn to an originally presented invention is considered to be non-responsive. (MPEP § 821.03). Since the above-mentioned amendment appears to be a *bona fide* attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

2. The remaining claims are not readable on the elected invention. The present claims require a comparison between a nucleic acid and one of the variant nucleic acids set forth in Table 7B. The claims as originally filed required a comparison between a nucleic acid and the wild-type GH1 nucleic acid. The originally filed claims also included claim 24 which required a comparison between a nucleic acid and any GH1 nucleic acid, wherein the GH1 nucleic acid was not defined in terms of its nucleic acid sequence. Accordingly, the originally filed and elected invention did not require a comparison with one of the variant sequences set forth in Table 7B. There are 139 variant sequences listed in Table 7B, wherein these variant sequences include different alterations at 10 distinct locations in the GH1 promoter, in addition to various mutations and polymorphisms. As amended it is unclear as to whether the method is one which compares a nucleic acid with one of the 139 haplotypes recited in Table 7B or one of the multitude of individual mutations in the promoter region, mutations in the coding and noncoding region or polymorphisms in the GH1 gene.

Accordingly, the following restriction requirement applies to the claims as amended.

RESTRICTION

3. Prior to setting forth the restriction requirement, it is pointed out that Applicants have presented the method claims in improper Markush format. See Ex parte Markush, 1925 C.D. 126 and In re Weber, 198 USPQ 334. The method claims are improperly joined as the claimed methods require the comparison of a nucleic acid to distinct target molecules. A reference against one target molecule would not be a reference against the other target molecule. Therefore, the restriction will be set forth for each of the various groups, irrespective of the improper format of the claims, because the claims do not recite proper species.

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

As discussed above, it is unclear as to what constitutes a "variant in Table 7B." For the purposes of this restriction requirement, the haplotypes in 7B will be considered to constitute the variants of Table 7B. Accordingly, Applicant is required to elect one of the 139 haplotypes set forth in Table 7B. For example, invention I is considered to be drawn to a method for comparing a target nucleic acid with a nucleic acid having the haplotype of patient 1(3). Invention II is considered to be drawn to a method which requires comparing a target nucleic acid with the nucleic acid having the haplotype of patient 1(6). If the phrase "variant in Table 7B" is intended to refer to one of the individual alterations set forth in Table 7B, then applicants are required to elect a single mutation or

polymorphism. For example, with respect to this interpretation of the claims, invention I would be drawn to a method which requires a comparison with a nucleic acid comprising a T/C mutation at position –168 of the GH1 gene.

The inventions are distinct, each from the other because the inventions require the analysis of nucleic acids which are structurally and functionally distinct from one another. Each of the variants set forth in Table 7B is considered to be patentably distinct since each variation occurs at a distinct location, has a distinct identity and modifies the GH1 gene in a distinct manner. For example, a method which detects a polymorphism at position –168 of the GH1 gene, would not render a method which detects a polymorphism at position -75 of the GH1 gene obvious. Accordingly, in the absence of evidence to the contrary, each variance is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.14.

Because these inventions are distinct for the reasons given above and have acquired a different status in the art as recognized divergent subject matter and because inventions require different keyword and sequence searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Furthermore, it is noted that claim 54 will be examined only to the extent that it reads on the elected invention of GH1F (SEQ ID NO: 35) and claim 58 will be examined only to the degree that it reads on the elected invention of methods for analyzing GH1 nucleic acids (see previous restriction requirement of September 27, 2002. Additionally, it is noted that claim 58 will be examined to the extent that it currently requires detecting any structurally undefined variation in the GH1 gene by comparing a test sample nucleic acid to a wild-type GH nucleic acid. However, if claim 58 is later amended to recite the detection of a specific variant, the above restriction will also apply to this claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. This phone number will be changed after January 13 to (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers
November 26, 2003

CARLA J. MYERS
PRIMARY EXAMINER